



U.S. Department  
of Transportation

400 Seventh Street, S.W.  
Washington, D.C. 20590

**APR 19 2005**

**Pipeline and  
Hazardous Materials  
Safety Administration**

Ms. Stephanie Kardos  
Manager, Regulatory Affairs  
OraSure Technologies, Inc.  
220 East First Street  
Bethlehem, PA 18015

Dear Ms. Kardos:

This is in response to your March 28, 2005, application for exemption (14177N) requesting an exemption from the requirements of 49 CFR Part 172 Subparts C through E for transportation of your Histofreezer device.

In accordance with 49 CFR 107.113(e) and (g), your application is denied for the following reasons:

Your proposal has not demonstrated it would provide a level of safety that is at least equal to that required by the HMR (see § 107.105(d)). Specifically, the use of a DOT 2Q container does not provide the additional packaging integrity to warrant relief from shipping papers, marking, and labeling. Such hazard communication is a cornerstone in ensuring the safe transportation of a hazardous material in commerce. Providing an exemption from the shipping paper, marking and labeling requirements of the HMR for these devices would not provide for a level of safety equivalent to that provided by the existing regulations and is not in the public interest.

If you have any questions, please do not hesitate to contact Ryan Posten at (202) 366-4535.

Sincerely,

Robert A. McGuire  
Associate Administrator for  
Hazardous Materials Safety